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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,307	09/26/2002	Edward Ingenito	10991-002US1	1962
23628	7590	01/09/2008		
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER VU, QUYNH-NHU HOANG	
			ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/069,307		INGENITO, EDWARD	
	Examiner		Art Unit	
	Quynh-Nhu H. Vu		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34, 55-58, 60-63 and 65-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34, 55-58, 60-63 and 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/20/07 & 9/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 7/13/07 have been entered.

Claims 1-34, 55-58, 60-63, 65-73 are present for examination.

Claims 35-54, 59, 64 are cancelled.

Previous allowed claims 1-34, 55-58, 60-63, 65-73 are being looked in a new light and a new rejection follows below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1- 3, 13-16, 18-19, 24-25, 31-34, 55-58, 60-63, 65-67, 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Perkins et al. (US 6,287,290).

Perkins discloses a methods, systems and kits for lung volume reduction that comprising: advancing a bronchoscope (col. 2, lines 15-20, col. 8, lines 18+) and introducing material through the bronchoscope into a diseased alveolar region within the targeted region (col. 2, lines 38-43, col. 10, lines 37+); wherein the material (fibrin glue) introduced through the bronchoscope induces collapse of the targeted region (col. 2, lines 30-35, col. 3, lines 22-58); promotes adhesion between one collapsed portion of the lung and another; and promotes fibrosis /fibrin glue in or around the collapsed region of the lung (col. 2, lines 37-43, col. 4, lines 10-20). An oxygen rich gas can be introduced prior to collapse (col. 6, line 59+ and col. 9, line 45+).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-12, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al.

Perkins meets the claim limitations as described above but fails to disclose the fibrin/fibrinogen comprises component of materials listed in claims 6-12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material listed in claims 6-12, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claims 4-5, 17, 20-21, 26-27, 29-30, 68, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson et al. (US 5,739,288).

Perkins meets the claim limitations as described above but fails to disclose the fibrin comprises a polypeptide growth factor, the use of fibrinogen and a fibrinogen activator such as thrombin.

Edwardson discloses a fibrin further comprises a polypeptide growth factor, a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 1, line 40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery times.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson in further view of Antanavich et al. (US 5,814,022).

Perkins in view of Edwardson meets the claim limitations as described above but fails to include the composition comprising 3-12 fibrinogen.

Antanavich discloses a method and apparatus for applying tissue sealant that includes that use of an adhesive protein solution having a fibrinogen content of from 3 to 12% with clot promoting factor XIIIa and further notes that one reason for this arrangement is that the strength of the sealant is proportional to the fibrinogen concentration. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 10, line 40) and Antanavich teaches an enhanced fibrin sealant composition a combination is proper. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to incorporate the concentration of fibrinogen as taught by Antanavich et al. into the invention of Perkins in order to have an adhesive protein solution that is less prone to clogging before administered to the therapeutic site as taught by Antanavich et al. Furthermore, It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Quynh-Nhu H. Vu
Examiner
Art Unit 3763



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